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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/982,965	12/02/1997	GEORGE H. LOWELL	359292000110	9909

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	08/982,965	LOWELL, GEORGE H.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *08 March 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *see attached*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

The Amendment filed February 17, 2004 in response to the Office Action of September 9, 2003 is acknowledged the amendments have not been entered as they do not deemed to place the application in better condition for appeal. The amendments are not entered as they do raise new issues that may require new search.

The Examiner and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Examiner Winkler, Group Art Unit 1648.**

Claims 1, 3-4, and 7-13 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Lowell et al. (U) or Lowell et al. (V) or Smith et al. (W) or Avraham et al. (X) in view of Ratner et al. (Y) for the reasons of record set forth in the prior Office Actions.

The amendments are drawn to the addition of process steps to the product claims. M.P.E.P. Section 2113 states that: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

The claimed invention is directed to compositions capable of eliciting antibodies. Applicant's claims are not directed to a vaccine or to a protective immune response to HIV. In Applicant's sole independent claim, claim 1, Applicant has claimed an immunogenic

composition comprising proteosomes, gp160 protein, and a pharmaceutical carrier. As such, the only requirement of the claimed invention is that the composition causes the production of antibodies to gpl60.

Each of the primary references also teaches the use of similar immunogenic proteosome-protein compositions. Both Lowell et al. (U) and Smith et al. (W) teach the use of proteosomes to enhance the immunogenicity of circumsporozoite peptides. Lowell et al. (V) teach the use of proteosomes to enhance the immunogenicity of membrane glycoprotein peptides. Avraham et al. (X) teach the use of proteosomes to enhance the immunogenicity of HIV-AIDS membrane glycoprotein peptides. Avraham et al. also teach the use of a carrier. The primary references do not teach an immunogenic proteosome-gpl60 composition. However, Ratner et al. (Y) teach the gene sequence for a glycosylated exterior membrane protein (page 282. column 1). This glycosylated exterior membrane protein is gp160. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the various immunogenic peptides disclosed in the primary references for the gp160 peptide of Ratner et al. because gp160 was known to be an envelope protein, and it is well known in the viral art that envelope proteins are highly immunogenic compounds. Avraham et al. provide motivation by teaching the use of immunogenic proteosome compositions in the context of HIV-AIDS. Furthermore, Ratner et al. provide motivation. By teaching that the complete nucleotide sequence of the HTLV-III provirus will provide useful information for the development of diagnostic and therapeutic reagents to AIDS (page 280,column 1).

Applicant argues that Smith et al. and Aversham et al. are silent as to the details of the technique employed in Applicant's invention. However, Applicant's sole independent claim (claim 1), does not claim a technique. Rather, claim 1 is directed towards a composition.

Applicant points to the unpredictable nature of antibody titers between peptides of different size. Applicant also point to variation in the degree of immunogenicity achieved by the different techniques. However, Applicant is reminded that there is a certain level of unpredictability and variation in any scientific experimentation-but that the degree of unpredictability and variation, in order to be considered nonobvious, must exceed the expectations of the person of ordinary skill in the art. In the present instance that degree has not been exceeded because, despite any unpredictability and variation, a person of ordinary skill in the art at the time of invention would not have been dissuaded or discouraged from substituting gp160 peptide of Ratrier et al. for the other peptides taught by the cited primary references to induce antibody production.

As stated in the prior Office Actions, dependent claims 10 and 11 only add further limitations that the complexes are formed by lyophlization or dialysis, both very well known techniques in the art for protein isolation, purification, or storage.

Dependent claim 12 only adds the further limitation that the complexes are formed by mixing. However, the limitation of "mixing" is a very well known technique in the art for combining two or more components and does not render the claim nonobvious.

Dependent claims 3, 4, and 13 only add the further limitation of an adjuvant. However, a person of ordinary skill in the art would have found it obvious to add any adjuvant to increase immunogenicity because, by definition, adjuvants increase immunogenicity.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 5/17/04